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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,596	02/15/2002	Alan D. Snow	PROTEO.P18CI	2850

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06/16/2004

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/077,596	Applicant(s) SNOW ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 42-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-41,55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on March 30, 2004 wherein claims 28-41 and 55-56 have been amended and claim 54 is cancelled.

Currently, claims 1-53 and 55-56 are pending in this application.

It is noted that claims 1-27, 42-49 and 50-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention of record in the previous Office Action dated September 30, 2003.

Claims 28-41 and 55-56 as amended now are examined on the merits herein.

Applicant's amendment filed March 30, 2004 with respect to the rejection of claims 31, 36-38, 39-41, and 54-56 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations, i.e., "analogous and derivatives", "substantially", and "or the like" of record stated in the Office Action dated September 30, 2003 have been fully considered and found persuasive to remove the rejection since these indefinite recitations have been removed from the claims. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681,569) for reasons of record stated in the Office Action dated September 30, 2003.

Kuznicki et al. discloses a composition **comprising** green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, col.2, lines 12-14; Example I, II, and III at col.10, and claims 1 and 5-6. Thus, the green tea composition of Kuznicki et al. **inherently** comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (10-100mg/kg of body weight of the subject), is disclosed in the Example I and III (see col. 10 lines 1-41) as shown in the calculation below:

Example III discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

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Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example I, the effective amount of catechins (or flavanols)

$$= 835\text{g} \times 0.097\% \text{ (see col.10 line 15 in particular)} = 0.8099 \text{ g} = 809.9 \text{ mg}$$

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

$$= 835\text{g} \times 0.35/100 \times 29/100 = 0.8475 \text{ g} = 847.5 \text{ mg.}$$

Since a standard person weight is 70 kg, the range of effective amounts of catechins is $10 \text{ mg/kg} \times 70 \text{ kg} = \underline{700 \text{ mg}}$ to $1000 \text{ mg/kg} \times 70 \text{ kg} = 70,000 \text{ mg}$.

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

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Thus, most importantly, Kuznicki's composition inherently comprising proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea.

Thus, Kuznicki et al. anticipates claims 28-41 and 55-56.

Response to Argument

Applicant's arguments filed March 30, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant's argument that the instant claims as amended now were limited to direct to Formula I or Formula II, is not persuasive. Note that the transitional phrases "**comprising**" is employed in the instant claimed composition, i.e., the independent claim 28 reads "A pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin, selected from..). Applicant is requested to note that the transitional term "comprising" is **inclusive or open-ended and does not exclude additional, unrecited elements or method steps**. See MPEP 2111.03.

Thus, the instant claimed composition read on the composition of Kuznicki et al. comprising green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate, and also proanthocyanidins oligomers having the formula I and II herein, because

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proanthocyanidins oligomers having the formula I and II herein are also extracted from green teas. Although the structural features of proanthocyanidins oligomers having the formula I and II herein have not been disclosed or identified by Kuznicki et al., proanthocyanidins oligomers having the formula I and II, are inherently **present** in the composition of Kuznicki et al. extracted from green teas. Note that the instant claimed composition is not drawn to a composition consisting of proanthocyanidins oligomers having the formula I and II.

Thus, Kuznicki et al. anticipates claims 28-41 and 55-56.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 for reasons of record stated in the Office Action dated September 30, 2003.

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by β -amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts (doses) of diminishing the toxicity of β -amyloid protein (see particularly page 1, the 2nd paragraph; claims 1-3 at page 1; page 2 [0001], [0002]), and a pharmaceutical carrier (i.e., water). See also page 7 [0028]; page 8 [0029]. Thus, the green tea composition in JP 10245342 inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea.

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JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, JP 10245342 anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed March 30, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the same rationale discussed in the rejection anticipated by Kuznicki et al.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. for reasons of record stated in the Office Action dated September 30, 2003.

Hashimoto et al. discloses a composition comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the oolong tea composition in Hashimoto et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from oolong tea.

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Hashimoto et al. also discloses that catechins therein are extracted from teas or other plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hashimoto et al. anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed March 30, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the same rationale discussed in the rejection anticipated by Kuznicki et al.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatano et al. for reasons of record stated in the Office Action dated September 30, 2003.

Hatano et al. discloses a composition for anti-HIV comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the composition in Hatano et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from *Camellia japonica* plants. See abstract.

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Hatano et al. also discloses that catechins therein are extracted from plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hatano et al. anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed March 30, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the same rationale discussed in the rejection anticipated by Kuznicki et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-41 and 55-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-15 of the

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copending Application No. 09/748,748 for reasons of record stated in the Office Action dated September 30, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other since the drug in 09/748,748 comprises those compounds of formula A, B, C, D or E which are also present in great tea extracts and obtained from the green teas.

For the same rationale discussed in the rejection anticipated by Kuznicki et al. the instant claims are seen to be anticipated by the claims 14-15 of the copending Application No. 09/748,748.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-41 and 54-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-39 of the copending Application No. 10/053,625 of record stated in the Office Action dated September 30, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent comprising or inherently comprising the same compounds herein and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition comprising the same compounds and a pharmaceutically acceptable excipients of the patent in amounts within the copending Application claim.

Thus, the instant claims are seen to be anticipated by the claims 31-39 of the copending Application No. 10/053,625.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-41 and 55-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,264,994 of record stated in the Office Action dated September 30, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a pharmaceutical composition comprising or inherently comprising the same compounds herein and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition comprising the same compounds and a pharmaceutically acceptable excipients of the patent in amounts within the copending Application claim.

Thus, the instant claims 28-41 and 55-56 are seen to be anticipated by the claims 1-18 of U.S. Patent No. 6,264,994.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

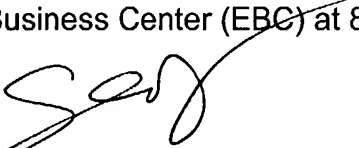
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 4, 2004

SHAOJIA ANNA JIANG
PATENT EXAMINER